

Remarks

This amendment is submitted in response to the Office Action mailed 31 January 2006, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on 30 April 2006. Submitted herewith is a Petition for a Three-Month Extension of Time extending the due date to 31 July 2006. Accordingly, this amendment is timely submitted.

The Applicant has fully considered the Office Action and cited references and submits this Reply and Amendment in response to the outstanding rejections. Reconsideration of the application for patent is requested. Applicants do not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further Applicants reserve the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Claims 1 through 11 are currently pending. Claims 18 – 25 have been withdrawn from consideration. Applicant would like to draw the Examiners attention to the Form PTOL-326 which accompanied the present Office Action. Item "4a" on the form lists withdrawn claims as 12-18. The Applicant has actually cancelled claims 12-18 and added claims 18-25 in a preliminary amendment on November 25, 2003. The Examiner had requested restriction of claims between Group I which consists of claims 1-11 and Group II which consists of claims 18-25. On September 30, 2005, the Applicant elected claims 1-11 for prosecution in response to the Examiner restriction requirement. In the restriction response letter filed on September 30, 2005, the Applicant, accidentally, requested "cancellation" of the claims 18-25 but intended that claims 18-25 be withdrawn from consideration. In addition, the Applicant takes note of the Examiner's comments that the restriction is being taken as one without traverse. The Applicant would like to indicate that the restriction requirement was intended to be made with traverse. The Applicant believes that the Examiner's search could be made of both the composition as claimed in claims 1-11 and the use thereof, as claimed in claims 18-25 without undue burden for the Examiner. The composition and its use is intimately related and that a search of references for the elements of claims 1- 11 could include a simultaneous search of the references concerning the intended use of the composition of claims 1-11 to treat the disease states of claims 18-25. The Applicants respectfully request that the Examiner enter the traversal of the Restriction Requirement.

Claims 2, 4 and 9 are herein cancelled. Claims 1, 3, 5 and 10 are amended to reflect the novelty and non-obvious nature of the invention. Claim 1 now incorporates the subject matter of claims 1 and 2. Support for the amendment to claim 3 may be found in line 3 on page 9 of the Specification. Claim 5 has been amended. Support for the amendment to claim 5 may be found in Examples 2 to 4 described on pages 21 to 23. Claim 10 now depends from claim 5. Support

for the amendment to claim 10 may be found in Examples 3 and 4 described on pages 21 to 23 of the Specification. Claim 26 has been newly added. Support for claim 26 may be found in Example 2 on page 21.

Claims rejections under 35-USC §102(b)

The Examiner has rejected claims 1, 3, 5, 8, and 11 under 35-USC §102(b) over Moro et al. The Applicant has amended the claims of the pending application. The Applicant believes that the changes to the claims now renders moot the Examiner's rejection on these grounds. The Moro reference describes the use of a composition which consists of 10% FOS and 90% GOS and wherein the ratio of the FOS:GOS oligosaccharide mixture is from 0 to 0.8 g per 100 mL of the composition, as defined in the text in the second paragraph and table 1 on page 292 of Moro. The present invention claims a composition comprising a FOS:GOS ratio of 0.2 to about 5.0. Moro specifically states that exactly 10:90 or 0.11 ratio was used in the experiment detailed in the reference and infers no equivalents. Also, the Applicants claim a composition which contains a FOS/GOS oligosaccharide mixture that comprises from 2 to 55% of the total composition as compared to the maximum of 0.8% in Moro. Therefore, the parameters of the experiment used in Moro do not read on the claims of the present invention. Applicants respectfully request that the Examiner withdraw the rejection of claims 1, 3, 5, 8, and 11 under 35-USC §102(b) over Moro et al.

The Examiner has rejected claims 1, 3, 5, 8, and 11 under 35-USC §102(b) over Boehm et al. The Applicant has amended the claims of the pending application. The Applicant believes that the changes to the claims, as described above for the rejection over Moro, also apply to the rejection over Boehm. Boehm describes an experiment using 0.11 ratio of FOS:GOS and wherein the FOS:GOS component of the formulation used therein is from 0 to 1.0% of the weight of the total composition of Boehm as specified in the last paragraph on page F178 and Table 1 on page F179 of Boehm. The parameters of the composition of Boehm do not read upon the claims of the present application. Applicants respectfully request that the Examiner withdraw the rejection of claims 1, 3, 5, 8, and 11 under 35-USC §102(b) over Boehm et al.

The Examiner has rejected claims 1, 5, 7-8, and 11 under 35-USC §102(b) over Rigo et al. The Applicant has amended the claims of the pending application. The Applicant believes that the changes to the claims, as described above for the rejection over Moro, also apply to the rejection over Rigo. Rigo describes an experiment using a composition which contains a FOS:GOS oligosaccharide mixture wherein the FOS:GOS component of the formulation used

therein is 0.4% of the weight of the total composition of Rigo, as specified in the first full paragraph on page 41 of Rigo. Rigo also indicates that another formulation of 0.8% FOS:GOS may be used (please refer to the same paragraph of Rigo). However, neither specified FOS:GOS composition reads upon the Applicants present claims. Therefore, the Applicants respectfully request that the Examiner withdraw the rejection of claims 1, 5, 7-8, and 11 under 35-USC §102(b) over Rigo et al.

Claims rejections under 35-USC §103

The Examiner has rejected claims 4, 6, and 9-10 under 35 USC §103 over Moro et al. Applicants respectfully submit that this rejection is improper because a prima facie case of obviousness has not been established. The three elements of a prima facie case of obviousness are: 1) some suggestion or motivation to modify the reference or combine the teachings; 2) a reasonable expectation of success and 3) the prior art references must teach or suggest all the claim limitations. *Fine* 837 F.2d 1071 (Fed.Cir 1988), *In re Jones* 958 F.2d 347 (Fed. Cir 1992). The Examiner has stated, even though Moro does not disclose the percentages and ratios of the Applicants invention that it would have been obvious to optimize the ratio. The Applicants disagree with the Examiner and respectfully request that the rejection on these grounds be withdrawn.

The Applicants' present invention claims a ratio of FOS GOS which is at least 2 to 25 times that of the disclosure of Moro. The Applicants claim use a percentage of FOS GOS mixture in the present invention which is at least 2.0 to nearly 70 times as concentrated as the formula used in Moro. Moro discloses a single very specific ratio and concentration. There is no suggestion in Moro that other concentrations could be successful for regulating intestinal flora as claimed in the present application. In fact, Moro state that the ratios and concentration of oligosaccharides should be similar to that found in human milk (please refer to page 292 second full paragraph). Thus, one skill in the art would not be motivated to use a different ration or concentration of FOS than that disclosed in Moro since there is no reasonable expectation of success if one chose the Applicants' ratios and percentages. The Applicants have specifically determined that the range of FOS GOS mixture as claimed in the present invention would increase beneficial bacteria in the human gut (please refer to pages 18 – 23). Based on the foregoing the Applicants' respectfully request that Examiner withdraw the rejection of claims 4, 6, and 9-10 under 35 USC §103 over Moro et al.

The Examiner has rejected claims 4, 6, and 9-10 under 35 USC §103 over Boehm et al. The Examiner has used the same argument as discussed above for Moro et al. to state that Boehm renders the Applicants' invention obvious. The Applicants disagree with the Examiner

and respectfully request that the Examiner withdraw the rejection of claims 4, 6, and 9-10 under 35 USC §103 on these grounds. The Examiner appears to indicate that it would be obvious to try to modify the disclosure of Boehm to arrive at the present invention. As discussed above, for Moro, Boehm et al. disclose that the ratio and percentage of oligosaccharides should be the same as that found in mother's milk (please refer to the Study Design section in the abstract on page F178 of Boehm). Thus, one of skill in the art would not be motivated to create the present invention since there is no suggestion that there would be a reasonable expectation of success if one altered the ratios and amounts as disclosed in Boehm. Boehm also uses a concentration of oligosaccharides that is at least two fold less than that disclosed in the present application. Based on the foregoing the Applicants' respectfully request that Examiner withdraw the rejection of claims 4, 6, and 9-10 under 35 USC §103 over Boehm et al.

The Examiner has rejected claim 2 under 35 USC §103 over Moro et al. in view of US Pat. No. 5,827,526 (US '526). The Examiner states that while Moro does not teach the use of FOS and GOS having a degree of polymerization of from 2 to 7. However, the Examiner indicates that US '526 does teach a polymerization of from 2 to 20. The Applicants disagree with the Examiner's determination and respectfully request that the rejection be withdrawn. Moro do not suggest or even hint at polymerization and US '526 specifies from 2- 20 of either FOS or GOS. As discussed above, Moro does not motivate one of skill in the art to create the Applicants' invention. US '526 discloses that only one of FOS or GOS should be employed. The Applicants have demonstrated that both FOS and GOS should be employed to achieve optimal results. This is not contemplated nor suggested by US '526. Based on the foregoing, the Applicants' respectfully request that Examiner withdraw the rejection of claims 4, 6, and 9-10 under 35 USC §103 over over Moro et al. in view of US Pat. No. 5,827,526.

The Examiner has rejected claim 2 under 35 USC §103 over Boehm et al. in view of US Pat. No. 5,827,526 (US '526). The Examiner makes this determination using the same analysis as for the rejection made for claim 2 over Moro in view of US '526. The Applicants disagree with the examiner and respectfully request that the Examiner withdraw the rejection. The Applicants herein apply the same discussion as made in the previous paragraph against the rejection of claim 2 over Moro. There is no suggestion or motivation of success, individually from the Boehm reference, as discussed above and US '526 does not contemplate that both FOS and GOS should the Applicants claimed degree of polymerization. Based on the foregoing, the Applicants' respectfully request that Examiner withdraw the rejection of claims 4, 6, and 9-10 under 35 USC §103 over over Moro et al. in view of US Pat. No. 5,827,526.

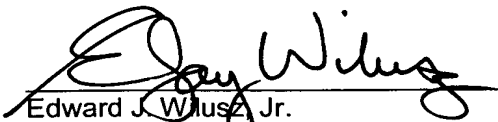
The Applicants believe that case in now in condition for allowance and respectfully request early notice to that effect.

The Examiner is herein authorized to charge Deposit Account No. 19-0134 in the name of Novartis Corporation for fees which may be properly assessable in the case and to refund fees paid in excess of amounts due.

If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,

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